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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,811

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Suketu P. Sanghvi

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10/02/2008

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EXAMINER

JAGOE, DONNA A

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

10/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<i>Office Action Summary</i>	Application No. 10/821,811	Applicant(s) SANGHVI ET AL.	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1,7,8,10,17-19,22,26,33-39,44,50,54-56,61-68,71-73,77,78,83-86,92-94,101-103,106,110,117-121,129,133,136,140-144,147,149,155,158,163-165,172,176,179,180,183,184,187-189,195,196,202,206-208,214,216,219,221,223,225,228,231,247,252,255-257,261,267,271-283,285,287,289,291,293,294,296,299,302-304,307-324 is/are pending in the application.

4a) Of the above claim(s) 1,7,8,10,17-19,22,26,33-39,44,50,54-56,61-68,71-73,77,78,83-86,92-94,101-103,106,110,117-121,129,133,136,140-144,147,149,155,158,163-165,172,176,179,180,183,184,187-189,195,196,202,206-208,214,216,219,221,223,225,228,247,252,255-257,261,267,271-283,285,287,289,291,293,294,296,299,302-304,307-315 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 231 and 316-324 is/are rejected.

7) ☐ Claim(s) 1, 7, 8, 10, 17-19, 22,26, 33-39, 44,50, 54-56, 61-68, 71-73, 77,78, 83-86, 92-94, 101-103, 106, 110, 117-121, 129, 133, 136, 140-144, 147, 149, 155, 158, 163 165, 172, 176, 179, 180, 183, 184, 187-189, 195, 196, 202, 206 208, 214, 216, 219, 221, 223, 225, 228, 247, 252, 255-257, 261, 267, 271-283, 285, 287, 289, 291, 293, 294, 296, 299, 302-304 and 307-315 is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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PTOL-326 (Rev. 08-06)

Office Action Summary

Part of Paper No./Mail Date 20080915

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/18/04,8/9/04,12/13/04,2/23/07,1/22/08.

DETAILED ACTION

Applicant's election without traverse of the group VI invention, Claims 231 and 316-324 in the reply filed on July 11, 2008 is acknowledged.

Claims 1, 7, 8, 10, 17-19, 22,26, 33-39, 44,50, 54-56, 61-68, 71-73, 77,78, 83-86, 92-94, 101-103, 106, 110, 117-121, 129, 133, 136, 140-144, 147, 149, 155, 158, 163, 165, 172, 176, 179, 180, 183, 184, 187-189, 195, 196, 202, 206 208, 214, 216, 219, 221, 223, 225, 228, 247, 252, 255-257, 261, 267, 271-283, 285, 287, 289, 291, 293, 294, 296, 299, 302-304 and 307-315 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 11, 2008.

Claims 231 and 316-324 are presented for examination.

Claim Objections

Claims 1, 7, 8, 10, 17-19, 22,26, 33-39, 44,50, 54-56, 61-68, 71-73, 77,78, 83-86, 92-94, 101-103, 106, 110, 117-121, 129, 133, 136, 140-144, 147, 149, 155, 158, 163, 165, 172, 176, 179, 180, 183, 184, 187-189, 195, 196, 202, 206 208, 214, 216, 219, 221, 223, 225, 228, 247, 252, 255-257, 261, 267, 271-283, 285, 287, 289, 291, 293, 294, 296, 299, 302-304 and 307-315 are objected to because of the following informalities: The amendment to the claims filed on July 11, 2008 does not comply with the requirements of 37 CFR 1.121(c) because the status of the claims is not clearly

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marked in all the claims, see for example, **the withdrawn claims are not indicated as “withdrawn”**.

Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) Claims . Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered)

(1) Claim listing. All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of “canceled ” or “not entered ” may be aggregated into one statement (e.g., Claims 1 –5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

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(2) When claim text with markings is required. All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of “currently amended, ” and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of “currently amended, ” or “withdrawn ” if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as “withdrawn — currently amended. ”

(3) When claim text in clean version is required . The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of “original, ” “withdrawn ” or “previously presented ” will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of “withdrawn ” or “previously presented.” Any claim added by amendment must be indicated with the status of “new ” and presented in clean version, i.e., without any underlining.

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- (4) When claim text shall not be presented; canceling a claim .
- (i) No claim text shall be presented for any claim in the claim listing with the status of “canceled ” or “not entered. ”
- (ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as “canceled ” will constitute an instruction to cancel the claim.
- (5) Reinstatement of previously canceled claim. A claim which was previously canceled may be reinstated only by adding the claim as a “new ” claim with a new claim number.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 231 and 316-324 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hermann et al. U.S. Patent No. 4,322,426 (cited in IDS dated 2/23/07) and Remington's Pharmaceutical Sciences (U)

Hermann et al. teach a pharmaceutical composition comprising 6-Desoxy-6 α -methylnaltrexone (see Example 1, column 10) formulated in a liquid for oral or parenteral administration (column 16, lines 34-38). Solutions for parenteral administration contain sodium EDTA (column 16, lines 56-63).

Hermann et al. does not teach the particular pH instantly claimed and does not teach the particular concentration of EDTA or derivative thereof. As recited in Remington's Pharmaceutical Sciences, Buffers are primarily used to stabilize a solution against the chemical degradation that would occur if the pH changed appreciably. Buffer systems should normally have as low a buffer capacity as feasible in order not to disturb significantly the body buffer systems when injected. Further, antioxidants are frequently required to preserve products because of the ease with which many drugs

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are oxidized. The sodium salt of ethylenediaminetetraacetic acid (EDTA) has been found to enhance the activity of antioxidants and in some cases, apparently by chelating metallic ions that would otherwise catalyze the oxidation reaction (page 1466 column 2, "buffers" and "antioxidants").

It would have been made obvious to one of ordinary skill in art at the time it was made to employ a chelating agent and to buffer a solution intended for parenteral administration motivated by the teaching of Remington's Pharmaceutical Sciences that sodium salt of EDTA enhances the activity of antioxidants and chelates metallic ions that would otherwise catalyze the oxidation reaction and buffering stabilizes the solution.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

September 15, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614